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EXAMINER

CORDERO GARCIA, MARCELA M

ART UNIT PAPER NUMBER

1654

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,304

Applicant(s)

STUPP ET AL.

Examiner

Marcela M. Cordero Garcia

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 19, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election with traverse of Group II, claims 9-16 in the reply filed on September 19, 2005 is acknowledged. The traversal is on the grounds that Applicant does not believe that the Examiner would be seriously burdened by a search for each of Groups I and III-VI since the subject matter of the search for at least the claims of Group I-III would greatly overlap and are in fact classified in the same class and subclass. The composition found in claims 9-16 would have to be searched for each of Examiner's designated Inventions, but at a minimum for Inventions I and III.

Examiner has carefully considered Applicant's arguments and has deemed them persuasive as far as rejoining groups I, II, and III. New groups have therefore been drawn as follows:

- I. Claims 1-21, drawn to a peptide amphiphile composition, classified, e.g., in class 514, subclass 1+.
- II. Claims 22-27, drawn to a nanofiber composition, classified, e.g., in class 977, subclass 1.
- III. Claims 28-35, drawn to a method of treating a patient with tissue engineered material, classified, e.g., in class 435, subclass 1.1.
- IV. Claims 36-40, drawn to a mineralizable bone-defect filler, classified, e.g., in class 606, subclass 86.

Claims 1-21 are drawn to Applicant's elected group. Claims 22-40 are withdrawn since they are not drawn to Applicant's elected group.

Claims 1-21 are presented for examination on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Hartgerink et al. (Science, 2001).

Hartgerink et al. teach a peptide amphiphile composition comprising:

a hydrophobic component; and

a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH, said peptide amphiphile self assembling to form a micelle. (See, e.g., Figure 1). Please note that the instantly claimed functional effects (i.e., micelle formation and having a net charge at physiological pH) would be inherent [at least in some cases] to the composition taught by Hartgerink et al.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 1-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Hartgerink et al. (PNAS, 2002).

Hartgerink et al. teach a peptide amphiphile composition comprising:

a hydrophobic component; and
a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH, said peptide amphiphile self assembling to form a micelle. (See, e.g., Figure 1). Please note that the instantly claimed functional effects (i.e., micelle formation and having a net charge at physiological pH) would be inherent [at least in some cases] to the composition taught by Hartgerink et al.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 1-7 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Fields et al. (US 6,096,863) or over Fields et al. (WO 98/07752).

Fields et al. teach a peptide amphiphile composition comprising:

a hydrophobic component; and
a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH, said peptide amphiphile self assembling to form a micelle. (See US 6,09863, e.g., column 2, lines 30-43, 59-64 and claims. See also WO 98/07752, e.g., page 3, lines 5-14, page 5, lines 18-26, claims). Please note that the instantly claimed functional effects (i.e., micelle formation at certain concentrations and ionization at physiological pH) would be inherent [at least in some cases] to the composition taught by Fields et al.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fields et al. (US 6,096,863) in view of Murata et al. (J Biol Chem, 1991)

Fields et al. beneficially teach a peptide amphiphile composition comprising:

a hydrophobic component; and

a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH, said peptide amphiphile self assembling to form a micelle (See US 6,09863, e.g., column 2, lines 30-43, 59-64 and claims. See also WO 98/07752, e.g., page 3, lines 5-14, page 5, lines 18-26, claims). Please note that the instantly claimed functional effects (e.g., amphiphilic and micellar properties, ionization at physiological pH and micelle formation at certain concentrations) would be intrinsic to the composition taught by Fields et al.

Fields et al. do not expressly teach inducing self assembly by agents consisting of oppositely charged peptide amphiphiles, cations, anions.

Murata et al. beneficially teach inducing self assembly by agents consisting of oppositely charged peptides amphiphiles, cations, anions (See, e.g., page 14357, lines 28-41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust particular conventional working conditions within such composition (e.g., selecting specific amino acid residues within the peptide portion of the composition to generate a given ionization at physiological pH, selecting cysteine as one of the residues to promote covalent bonding thereof, inducing micelle formation by changing the chemical environment, such as concentrating the solution or adding an oppositely charged amphiphile [see Murata as above] and/or creating a peptide with a specific conical super-secondary structure) based upon the overall beneficial teachings provided by Fields et al. [e.g., WO 98/07752 page 9, lines 19-25]. These types of adjustments are deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the reference, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 102/103

Claims 1-21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yamada et al. (Chem Letters, 1984).

Yamada et al. teach a peptide amphiphile composition comprising:

a hydrophobic component; and a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH, said peptide amphiphile self assembling to form a micelle. (See, e.g., pages 1-3 and Fig. 1 and compare to Figures in the application, e.g., Figs. 3-5 and 7-11 and in Hartgerink et al. PNAS, 2002).

Therefore, the reference is deemed to anticipate the instant claims above.

In the alternative, even if the claimed composition is not identical to the referenced composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to inherently possess the same characteristics of the claimed composition particularly in view of similar characteristics which they have been shown to share. If not expressly taught, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust particular conventional working conditions within such composition [e.g., inducing assembly by adding an oppositely charged amphiphile] based upon the overall beneficial teachings provided by Yamada et al. (see, e.g., pages 1-3). These types of adjustments are deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. Thus, the claimed composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear and convincing evidence to the contrary.

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With respect to the art rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' micelles (within the claimed composition) differs and, if so, to what extent, from the micelles disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicant.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 11/005,552. Although the conflicting claims are not identical,

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they are not patentably distinct from each other because both claimed inventions are drawn to a peptide amphiphile composition comprising a hydrophobic and a hydrophilic component bonded to said hydrophilic component having a net charge at physiological pH, said peptide amphiphile forming a micelle. Further, the instantly claimed composition encompasses and/or is encompassed by the composition of Application '552.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/005,314. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed inventions are drawn to a peptide amphiphile composition comprising a hydrophobic and a hydrophilic component bonded to said hydrophilic component having a net charge at physiological pH, said peptide amphiphile forming a micelle. Further, the instantly claimed composition encompasses and/or is encompassed by the composition of Application '314.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-21 are provisionally rejected on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 10/368,517. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed inventions are drawn to a peptide amphiphile composition comprising a hydrophobic and a hydrophilic component bonded to said hydrophilic component having a net charge at physiological pH, said peptide amphiphile forming a micelle. Further, the instantly claimed composition encompasses and/or is encompassed by the composition of Application '517.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,890,654. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed inventions comprise a peptide amphiphile composition comprising a hydrophobic and a hydrophilic component bonded to said hydrophilic component having a net charge at physiological pH, said peptide amphiphile forming a micelle. Further, the instantly claimed composition encompasses and/or is encompassed by the composition of US '654.

Please note that, due to the large volume of related applications that Applicants encompassing similar subject matter, Examiner requests that Applicants indicate any

other relevant applications containing overlapping claimed subject matter therein and that would therefore be object to double patenting rejections.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MMCG 11/05



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